

## HOUSE OF REPRESENTATIVES STAFF ANALYSIS

**BILL #:** HB 845 w/CS Biomedical Research/Diseases

**SPONSOR(S):** Farkas and others

**TIED BILLS:** None.

**IDEN./SIM. BILLS:** SB 2142 (s)

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REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care	18 Y, 0 N w/CS	Rawlins	Collins
2) Commerce		Winker	Whitfield
3)			
4)			
5)			

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### SUMMARY ANALYSIS

The bill establishes the Center for Universal Research to Eradicate Disease (CURED). The purpose of the center is to coordinate, improve, expand, and monitor all biomedical research programs within the state, facilitate funding opportunities, and foster improved technology transfer of research findings into clinical trials and widespread public use.

The center must hold an annual biomedical technology summit in Florida to which biomedical researchers, biomedical technology companies, business incubators, pharmaceutical manufacturers, and others around the nation and world are invited to share biomedical research findings. The center must encourage clinical trials in Florida on research that holds promise of curing a disease or condition. The center must facilitate partnerships between researchers, treating physicians, and community hospitals for the purpose of sharing new techniques and new research findings, as well as coordinating voluntary donations to ensure an adequate supply of adult stem cells, cord blood, and other tissues needed for biomedical research.

The center must also encourage the discovery and production in Florida of vaccines that prevent disease. The center must monitor the supply and demand for types of human tissue relating to research, including stem cell research, and other needs of researchers.

The funding of the Center is through private, state, and federal sources. The center will serve as a registry of all known biomedical grant opportunities and may assist any public or private biomedical research program in this state in preparing grant requests. The center must maintain a website with links to peer-reviewed biomedical research. The website must contain a list of all known biomedical research being conducted in Florida and must facilitate communication among researchers and other interested parties.

The center must submit an annual report to the Governor, the President of the Senate, and the Speaker of the House of Representatives no later than January 15 that contains recommendations for legislative change necessary to foster a positive climate for biomedical research in Florida. The Center may outsource duties to a private entity or state university.

The bill requires that the long-term goals of the Florida Biomedical Research Program include the expansion of biomedical knowledge relating to cures, in addition to prevention, diagnosis, and treatment, of diseases related to tobacco use. The bill specifies that research aimed at preventing or finding cures for diseases have a priority in grants awarded by the program.

The Department of Health estimates a fiscal impact of \$1,600 for travel expenses for department employees attending the statewide meeting.

The bill provides for an effective date of July 1, 2003.

**This document does not reflect the intent or official position of the bill sponsor or House of Representatives.**

**STORAGE NAME:** h0845b.com.doc

**DATE:** April 21, 2003

## FULL ANALYSIS

### I. SUBSTANTIVE ANALYSIS

#### A. DOES THE BILL:

- |                                      |   |  |                              |
|--------------------------------------|---|--|------------------------------|
| 1. Reduce government?                | Yes <input type="checkbox"/>            | No <input checked="" type="checkbox"/> | N/A <input type="checkbox"/> |
| 2. Lower taxes?                      | Yes <input type="checkbox"/>            | No <input checked="" type="checkbox"/> | N/A <input type="checkbox"/> |
| 3. Expand individual freedom?        | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/>            | N/A <input type="checkbox"/> |
| 4. Increase personal responsibility? | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/>            | N/A <input type="checkbox"/> |
| 5. Empower families?                 | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/>            | N/A <input type="checkbox"/> |

For any principle that received a "no" above, please explain:

This bill expands the role of government by creating the Center for Universal Research to Eradicate Disease.

This bill does not lower taxes, rather uses additional tax dollar to fund the Center for Universal Research to Eradicate Disease.

#### B. EFFECT OF PROPOSED CHANGES:

The bill creates s. 215.5605, F.S., to establish the Center for Universal Research to Eradicate Disease (CURED). The purpose of the center is to coordinate, improve, expand, and monitor all biomedical research programs within the state, facilitate funding opportunities, and foster improved technology transfer of research findings into clinical trials and widespread public use. The goal of the center is to find cures for diseases such as cancer, heart disease, lung disease, diabetes, and neurological disorders, including Alzheimer's disease, epilepsy, and Parkinson's disease.

The bill requires the center to hold an annual biomedical technology summit in Florida to which biomedical researchers, biomedical technology companies, business incubators, pharmaceutical manufacturers, and others around the nation and world are invited to share biomedical research findings in order to expedite the discovery of cures for diseases. Summit attendees will be required to cover the costs of their attendance or obtain sponsorship for their attendance at the summit.

The bill requires the center to:

- o encourage clinical trials in Florida on research that holds promise of curing a disease or condition;
- o facilitate partnerships between researchers, treating physicians, and community hospitals for the purpose of sharing new techniques and new research findings;
- o coordinate the voluntary donations to ensure an adequate supply of adult human stem cells, cord blood, and other tissues needed for biomedical research; and
- o encourage the discovery and production in Florida of vaccines that prevent diseases.

The bill requires the center to monitor the supply and demand for types of human tissue relating to research, including adult human stem cell research, and other needs of researchers. If the center determines that there is a need for the increased donation of adult human tissue, it must notify hospitals licensed under ch. 395, F.S., that have entered into partnership agreements with research institutes conducting human stem cell research located in the same geographic region as to the researchers' need for the adult stem cells or other adult tissues. The hospitals must then implement programs that encourage voluntary donations of cord blood or other needed adult tissues.

The bill requires that the center be funded through private, state, and federal sources. The center will serve as a registry of all known biomedical grant opportunities and may assist any public or private

biomedical research program in this state in preparing grant requests. The center must maintain a website with links to peer-reviewed biomedical research. The website must contain a list of all known biomedical research being conducted in Florida and must facilitate communication among researchers and other interested parties.

The bill requires the center to submit an annual report to the Governor, the President of the Senate, and the Speaker of the House of Representatives no later than January 15, which contains recommendations for legislative change necessary to foster a positive climate for biomedical research in Florida. The duties of the center may be outsourced to a private entity or state university.

The bill creates an advisory council within the center consisting of the members of the board of directors of the Florida Research Consortium, Inc., and at least one representative from:

- The Emerging Technology Commission;
- Enterprise Florida, Inc.;
- BioFlorida;
- The Florida Biomedical Research Advisory Council;
- The Florida Medical Foundation; and
- Pharmaceutical Research and Manufacturers of America.

The bill requires the advisory council to meet annually, that members of the council will serve without compensation, and that each organization represented on the advisory council must cover all expenses of its representative.

The bill amends s. 215.5602, F.S., which creates the Florida Biomedical Research Program, to require that the long-term goals of the program include the expansion of biomedical knowledge relating to cures, in addition to diagnosis and treatment, of diseases related to tobacco use, including cancer, cardiovascular disease, stroke, and pulmonary disease. The bill requires that priority be given to research designed to prevent or cure disease.

The effective date of the bill is July 1, 2003.

### **Coordination of Biomedical Research**

There is a positive impact to the economy and the health of the population in the area by conducting biomedical research and the resultant discoveries, products, or treatments. For both health and economic reasons, governments have an interest in furthering the work of biomedical researchers and in helping researchers collaborate and share resources. A number of states have initiatives to coordinate cancer research. Some state governments as well as private foundations, and companies are addressing the need of researchers who are conducting stem cell research.

### **Stem Cell Research**

Stem cells are cells that have the ability to divide for infinite periods in culture. They give rise to specialized cells. Research involving stem cells shows the possibility of treating diseases and conditions such as Alzheimer's and Parkinson's diseases, spinal cord injury, stroke, burns, heart disease, and arthritis. Growing an organ is a possibility from using stem cells, which has implications for tremendous changes in organ transplants.

A significant debate about stem cells involves the source of the cells. The harvesting of human stem cells occurs through human embryos (embryonic stem cells) or from the tissue of an adult (adult stem cells). Human embryos are the source for pluripotent stem cells—cells that are capable of giving rise to most tissues of the human organism. The development of embryos for the sole purpose of harvesting the stem cells has raised ethical issues since the harvesting process destroys the embryo. In August 2001, President George W. Bush announced that he would allow federal funding of research using the

60 existing stem cell lines. Thus, federal funds will not be used for stem cell research that involves the destruction of human embryos.

In November 2001, President George W. Bush created The President's Council on Bioethics for the purpose of advising the President on issues that may emerge as a consequence of advances in biomedical science and technology. (Executive Order 13237) In particular, through Presidential authorization, the council studies ethical issues connected with specific technological activities such as embryo and stem cell research. After studying the issue of human cloning, a majority of the council voted to ban cloning for the production of children and to place a 4-year moratorium on cloning for biomedical research. A minority of the council voted to ban cloning for the production of children and to regulate the use of cloned embryos for research.

### **The Florida Biomedical Research Program/Florida Biomedical Research Advisory Council**

The 1999 Legislature established the Lawton Chiles Endowment Fund (ch. 99-167, L.O.F.), through which the state will use funds received as a result of its settlement with the tobacco industry to enhance or support expansions in children's health care programs, child welfare programs, community-based health and human service initiatives, and biomedical research.

Section 215.5602, F.S., establishes the Florida Biomedical Research Program funded from earnings of the endowment fund and provides that funds appropriated to the program be devoted to competitive grants and fellowships in research relating to diagnosis and treatment of tobacco-related illnesses including cancer, cardiovascular disease, stroke, and pulmonary disease. The Biomedical Research Advisory Council in the Department of Health assists the Secretary in establishing criteria and guidelines for the competitive grant programs. An open, objective peer-review process awards grants and fellowships based on scientific merit. The council is required to submit a progress report to the Governor, Secretary of the Department of Health, President of the Senate, and Speaker of the House of Representatives by February 1 of each year.

### **The Emerging Technology Commission**

Under s. 1004.225, F.S., the 2002 Legislature passed the "Florida Technology Development Act." The Act provides for the following:

- Defines the term "center of excellence" to mean a program that, among its functions:
  - Facilitates the identification of collaborative research opportunities between universities and businesses.
  - Facilitates the acquisition of public and private funding for collaborative research opportunities and maximizes the leveraging of such funds.
  - Creates partnerships between industrial and governmental entities to advance knowledge and research and to move technologies from academic laboratories and research centers to commercial sectors.
  - Stimulates and supports new venture creation through partnerships with venture capital firms and other business, governmental, and educational entities.
  - Assists in the enhancement of advanced academic curricula through improved communication between academia and businesses.
  - Increases the number of graduates and faculty researchers in advanced technology programs while ensuring that a larger percentage of such graduates pursue careers in Florida industries.
  - Recruits and retains eminent scholars in advanced technology disciplines.
  - Provides capital facilities necessary to support research and development.

- Creates the Emerging Technology Commission (commission) within the Governor's Office for the purpose of guiding the establishment of centers of excellence within, and in collaboration with, the State University System. The commission consists of:
  - Nine regular members who must be recognized business leaders, industrial researchers, academic researchers, scientists, or engineers. The regular members include four regular members and the chair appointed by the Governor; two regular members appointed by the House Speaker; and two regular members appointed by the Senate President.
  - The Secretary of Education as an ex officio nonvoting member, to be replaced, effective January 7, 2003, by the Commissioner of Education as an ex officio nonvoting member.
  - As ex officio nonvoting members, the state senator and state representative who serve as members of the Florida Research Consortium, Inc.
- Provides that the Florida Research Consortium, Inc., must provide a report to the commission, which describes and prioritizes factors that contribute to the success of the creation of centers of excellence. At a minimum, the factors must include:
  - Maturity of existing university programs relating to a proposed center of excellence.
  - Existing amount of university resources dedicated to activities relating to a proposed center of excellence.
  - Comprehensiveness and effectiveness of site plans relating to a proposed center of excellence.
  - Regional economic structure and climate.
  - The degree to which a university proposed to house a center of excellence identifies and seizes opportunities to collaborate with other public or private entities for research purposes.
  - The presence of a comprehensive performance and accountability measurement system.
  - The use of an integrated research and development strategy utilizing multiple levels of the educational system.
  - The ability of a university proposed to house a center of excellence to raise research funds and leverage public and private investment dollars to support advanced and emerging technological research and development projects.
  - The degree to which a university proposed to house a center of excellence transfers advanced and emerging technologies from its laboratories to the commercial sector.
  - The degree to which a university proposed to house a center of excellence stimulates and supports new venture creation.
  - The existence of a plan to enhance academic curricula by improving communication between academia and industry.
  - The existence of a plan to increase the number, quality, and retention rate of faculty, graduate students, and eminent scholars in advanced and emerging technology-based disciplines.
  - The existence of a plan to increase the likelihood of faculty, graduate students, and eminent scholars pursuing private-sector careers in the state.
  - Ability to provide capital facilities necessary to support research and development.
- Provides that the commission develop and approve criteria for evaluating university-submitted proposals for creating centers of excellence. When developing such criteria, the commission must consider the report provided by Florida Research Consortium, Inc.

- Provides that the commission must submit to the State Board of Education at least two, but no more than five, recommended plans for the establishment of one or more centers of excellence in the state. Recommended plans must specifically address the evaluation criteria developed by the commission and delineate how funding would be used to develop the centers of excellence.
- Provides that the State Board of Education must develop and approve a final plan for the establishment of one or more centers of excellence in the state and authorize expenditures for implementation of the plan. When developing this final plan, the board must consider the commission's recommended plans and hold at least one public hearing for the purpose of soliciting expert testimony. The final plan must include performance and accountability measures that can be used to assess the progress of plan implementation and the success of the centers of excellence established under the final plan

According to information from the State Board of Education, based on a recommendation by the Emerging Technology Commission, the board approved the creation of three Centers of Excellence funded at \$10 million each. The three centers include the University of Florida's Center of Excellence in Regenerative Healthy Biotechnology, the University of Central Florida's Florida Photonics Center of Excellence, and the Florida Atlantic University's Center of Excellence in Biomedical and Marine Biotechnology.

### **ITFlorida and The Florida Research Consortium**

ITFlorida is a private umbrella organization comprised of both public and private technology leaders for high-tech in Florida. ITFlorida's stated mission is to make Florida a leader in high tech advancement, providing guidance to the state on technology issues and initiatives, guiding the Governor, the Legislature, and Enterprise Florida on the strategic technology direction and initiatives of the state and working to ensure the successful integration of technology infrastructure statewide.

The Florida Research Consortium, Inc., is private not-for-profit advisory board to ITFlorida.com, Inc., and is composed of volunteer university heads and industry leaders whose goal is to establish progressive research programs at Florida's universities. These programs are to focus on attracting leading scholars and researchers in technology-based disciplines to Florida's universities in order to build the state's knowledge base; endowing faculty and research chairs in targeted disciplines; facilitating the work of technology-transfer offices at member universities; promoting collaboration between academic and industrial researchers, scientists, and engineers; and promoting collaboration between Florida industry and academia to facilitate the development and deployment of new technologies.

The Florida Research Consortium's mission is to advise the Legislature and Office of the Governor on strategic policy initiatives for expanding and strengthening Florida's high-tech industries. The consortium aims to identify specific disciplines in science and technology where Florida has the greatest potential to achieve economic and academic successes and to promote collaboration between academic and industrial researchers, scientists, and engineers.

### **Enterprise Florida, Inc.**

Enterprise Florida, Inc., created under part VII of ch. 288, F.S., is a partnership between Florida's business and government leaders and is the principal economic development organization for the State of Florida. The organization's mission is to increase economic opportunities for all Floridians by supporting the creation of quality jobs, a well-trained workforce, and globally competitive businesses. It pursues its mission in cooperation with its statewide network of economic development partners.

## **BioFlorida**

BioFlorida's mission is to promote biotechnology and related science in Florida by creating a favorable business and legislative environment; to provide the platform for business, academia, and government to work jointly to support and encourage development of existing companies in the state and to attract new business and organizations to Florida.

## **The Florida Medical Foundation**

The Florida Medical Foundation is the Florida Medical Association's philanthropic organization for medical education, research, community service, and physician support programs. The foundation emphasizes support for physicians at all stages of their professional careers. The foundation has a current project relating to doctor patient communications as a way of addressing the problem of low health literacy among patients.

## **Pharmaceutical Research and Manufacturers of America**

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that improve the health and longevity of patients. The industry invested more than \$30 billion in 2001 in discovering and developing new medicines. PhRMA companies are involved in the search for new cures.

According to a June 2000 publication entitled "Business Facilities," Florida ranked #6 in a state for growth in the pharmaceutical and medical devices industry for the following reasons. Pharmaceutical and medical device manufacturers in general want to be close to their customer base and Florida is high on the list of states showing growth in this industry. Growth in the industry in Florida is influenced greatly by a sizeable population of retirees that is continually growing, many of whom need advanced medical care. This population gives medical manufacturers an important incentive to attain or maintain a strong presence in the state.

According to the publication, Florida has also made strides in establishing itself as a hotbed of advanced research and development through an elaborate network of partnerships between the state's universities, research hospitals, businesses, and government agencies. Florida's State University System is devoting substantial resources to biomedical research, with four of the state's universities engaged in sponsored medical research and linked to various technology-transfer centers and parks located throughout the state.

According to the publication, Florida is also home to some of the nation's leading research hospitals, including Shands, the Mayo Clinic, Jackson Memorial, and others.

According to the publication, medical manufacturing expansion announcements in 2000 included: Nephron Pharmaceutical Corporation who in 2000 announced a \$12 million expansion that resulted in 75 new jobs in Orlando; Medic Master/Aero Products who announced in 2000 a \$1.5 million expansion to its rescue vehicle manufacturing plant that resulted in 105 new jobs in Orlando; and WOM, GmbH, a German manufacturer of surgical medical devices who invested \$1.5 million to start up a U.S. headquarters facility in the Metro Orlando area.

### C. SECTION DIRECTORY:

**Section 1.** Creates s. 215.5605, F.S., providing Legislative findings and intent; creating the Center for Universal Research to Eradicate Disease; providing duties of the center; and creating an advisory council.

**Section 2.** Amends s. 215.5602, F.S., expanding the long-term goals of the Florida Biomedical Research Program to include the cure of specified diseases; requiring that priority for research under the Florida Biomedical Research Program be fore the prevention or cure of a disease.

**Section 3.** Provides for an effective date of July 1, 2003.

## II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

### A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

The Department of Health estimates a fiscal impact of \$1,600 for travel expenses for department employee attending the statewide meeting.

### B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

### C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Private entities involved in biomedical research or furnishing supplies to biomedical researchers could benefit from the coordination that would be provided by the Center for Universal Research to Eradicate Disease.

### D. FISCAL COMMENTS:

None

## III. COMMENTS

### A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or to take an action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenues.

2. Other:

None.

### B. RULE-MAKING AUTHORITY:

None.

### C. DRAFTING ISSUES OR OTHER COMMENTS:

The Florida Department of Health (DOH) has expressed the following concerns and questions on the bill:

- The bill does not specify where the CURED is to be located in state government.
- On lines 85-87 of the bill, certain hospitals will be required to “implement programs that encourage voluntary donations of cord blood or other needed adult tissues.” DOH questions how this will be enforced and that the bill does not contain a penalty for not implementing such programs.
- On lines 91-93 of the bill, CURED “may assist any public or private biomedical research program in this state in preparing grant requests.” DOH raises the issue of a potential conflict of interest between CURED Advisory Council members (especially the Florida Biomedical Research Program (BRAC) member) and any grant award functions that may be carried out by or on behalf of CURED and other state programs, such as BRAC.
- On lines 104 and 105 of the bill concerning outsourcing CURED duties, DOH raises the point that the bill does not specify who will be responsible for the outsourcing in terms of issuing an Invitation to negotiate, processing the contract, or managing the contract. Neither does the bill specify what CURED duties may be outsourced.
- On lines 106 and 107 of the bill, an advisory council is established within the CURED. DOH raises the point that the bill does not provide for DOH representation on the advisory council, does specify who appoints the council members in addition to the board of directors of the Florida Research Consortium, and does not specify a term for members of the advisory council.

Finally, DOH makes the point that, currently, grants under the Florida Biomedical Research Program are based on the scientific merit of research proposals. The bill requires that priority for the grants be given to proposals designed to prevent or cure a disease. Scientists conducting biomedical research investigate aspects of biological processes and diseases without knowing whether a particular project might eventually lead to better prevention, earlier diagnosis, more effective treatment, or a cure. In practice, all biomedical research is intended to lead to prevention, treatment or cure of a disease. Restricting or prioritizing biomedical research grants to proposals that are aimed at only prevention or cure could have the effect of withholding biomedical research grant funds from important areas of biomedical research inquiry. The Florida Department of Health recommends that lines 147 and 148 be removed from the bill.

### IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

On April 9, 2003, the Committee on Health Care reported the bill favorably with a committee substitute that explicitly provides that only human (adult) stem cell research would be supported through the Center for Universal Research to Eradicate Disease.